ADDIS ABABA UNIVERSITY, COLLEGE OF HEALTH SCIENCES, SCHOOL OF MEDICINE, DEPARTMENT OF ANATOMY

FOOT MECHANICS IN INDIVIDUALS WITH TYPE-1 AND TYPE-2 DIABETES MELLITUS: A COMPARATIVE STUDY

BY: Biruk Endalkachew (BSc.)

July, 2020
Addis Ababa, Ethiopia

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This thesis is **submitted to the department of Anatomy, school of medicine, college of health science, Addis Ababa University for the partial fulfillment of the requirements for the degree of Master of Science (MSc.) in Human Anatomy**

BY: Biruk Endalkachew (BSc.)

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Addis Ababa, Ethiopia

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Declaration

This is to certify that the dissertation is prepared by Biruk Endalkachew, entitled, "Foot Mechanics in Individuals with Type-1 and Type-2 Diabetes Mellitus: A Comparative Study" and submitted in partial fulfillment of the prerequisites for the degree of Masters of Science in Anatomy complies with the regulation of the University and meets the accepted standards with respect to originality and tone. This dissertation has not been presented for a grade in any other University, and that all sources of fabrics used for the thesis have been fully recognized.

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Abbreviations and Acronyms

- CG……. Clinical Guidelines
- DOH……... Department Of Health
- DM……. Diabetes Mellitus
- DPN……...Diabetic Peripheral Neuropathy
- DFCs…….. Diabetic Foot Complications
- DFU……...Diabetic Foot Ulceration
- FLEB……..Functional Lower Extremity Biomechanics
- MTUTH……..Mizan-Tepi University Teaching Hospital
- NHS……... National Health Service
- NICE……..National Institute of Healthcare Excellence
- NSF……. National Service Framework
- PAD……..... Peripheral Arterial disease
- PN…….....Peripheral Neuropathy
- PVD…….....Peripheral Vascular Disease
- T1DM……. Type 1 Diabetes Mellitus
- T2DM……. Type 2 diabetes Mellitus
- ROM…….. Range Of Motion
- WHO……..World Health Organization

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ABSTRACT

Introduction: Foot is a complex anatomical and biomechanical structure. There are 26 bones, 33 Joints, more than 100 ligaments, tendons and muscles in each foot. The biomechanics of diabetic foot is different from that of the non-diabetic foot. Changes in foot posture and architecture as a result of the diabetics impact on the normal biomechanics of walking and weight bearing on the foot.

Aim of the study: This study was conducted to assess and compare Anatomical and mechanical foot change in individuals with diabetes mellitus type-1 and type-2 in Mizan-Tepi University teaching hospital, Bench-Sheko zone, South-west, Ethiopia.

Materials and Methods: Institutional based cross sectional comparative study was conducted from June 1st 2019 up to November 30st, 2019 in Mizan-Tepi university teaching Hospital. The study participants were selected by using double population proportion formula sampling technique, who were 294 people diagnosed as diabetics (Type-1 and Type-2). Besides, data were collected by using structured questionnaires and diabetic foot assessment checklists.

Results: One hundred seventy-eights (60.5%), were males with the mean age (±SD) 43 (±14. 5) Years. 63.2% were illiterate, 19.4% completed primary school, 11.6% completed secondary school, and 5.8% were university graduate. Out of 294 participants with DM, 31.3% were obese or overweight, and 33.7% were diagnosed in the past 6-10 years. Among the study participants, 32.6% had PN, 22.5% had PAD, 55.1% had DFUs, and 46% had a deformity (15% Claw\hammer toe, 12.3% hallux valgus, 11% callus, and 8.2% pes cavus). Around 62.3% had good knowledge and 55.6% had identified good practice of DM foot care.

Conclusion: The current study showed that Type-2 diabetes patients have higher prevalence in developing diabetes related foot complications (like Claw\hammer toe, Hallux valgus, Callus, and pes cavus). However, Type-1 diabetes patients have increment in understanding the effects of diabetes on foot health and identifying appropriate foot care practice mobility as compared to Type-2 diabetes patients. Therefore, understanding foot mechanics is an important component of the examination and overall care of diabetic foot.

Keywords: Diabetes Mellitus, Foot Mechanics

1. Introduction

1.1. Background

Foot is a complex anatomical and biomechanical structure. There are 26 bones, 33 Joints and more than 100 ligaments, tendons and muscles in each foot as (Nilasenal et al., 2010) Again, (Sumpio, 2012) claims that, foot acts to transmit force between the lower limb and the ground, allowing stable ambulation and stance. Also, Foot acts as the foundation of the erect human body – its intrinsic structure and positioning can either directly or indirectly influence all joints of the lower limb, pelvis and spine as (Shavelson et al., 2011) confirmed.

In addition, effective gait relies on the ability of joints, muscles, tendons and ligaments to react to changes in extrinsic moments during mobility (Shavelson et al., 2011).During gait the foot functions as a flexible shock-absorber, deforming to uneven surfaces before undergoing a series of biomechanical changes which allow it to act as a rigid lever to exert force (Sumpio, 2012).On average, we walk 10000 steps per day, 1000000 steps per year and 115000 miles in our lifetime. The foot stands 3-4 times body weight during running (Sumpio, 2012).

Also, the ankle is the primary articulation responsible for the transmission of forces from the ground for the remainder of the lower extremity. It is subjected to greater forces per square cm than any other joint of the body (i.e. Hip = 2 - 3 X body weight=1100 mm^2, Knee = 3 - 4 X body weight=1120 mm^2 and Ankle = 5 - 7 X body weight=350 mm^2

Moreover, biomechanics is the science of applying the scientific laws of Physics, Architecture, and Engineering and Mechanics principles of living subjects (Sumpio, 2012).Biomechanically, the foot can be divided into functional segments in two main ways; the first divides it at the Mid-tarsal Joint into Rear foot and forefoot; the second divides the foot at the 2^{nd} and 3^{rd} rays into medial and lateral arch segments (Sumpio, 2012).

Besides, these two arches are connected by a transverse roof of bone, and the surface underneath these osseous supports, architecturally, is known as the vault of the foot, and it is centered and supported by healthy, soft tissues, provides a lifetime foundation for upright weight bearing and function. In contrast, if the vault is allowed to become off-centered exhibiting excess stiffness, flexibility, collapse or arch, on a case to case basis, the resulting stressful compensations in pedal

and postural bones, joints, muscles, tendons and ligaments provides an ever increasing burden to society as we live longer and more active lives (Sumpio, 2012).

Accordingly, changes in foot posture and architecture as a result of the diabetics impact on the normal biomechanics of walking and weight bearing on the foot and instructive for those involved in the management of the diabetic foot (Luigi et al., 2009).

In line with these, diabetes has a detrimental effect on multiple physiological systems, and also been known to be a potentially lethal disease for more than a thousand years. The complications associated with diabetes include cardiovascular diseases, retinopathy, nephropathy, and peripheral neuropathy (Bowling, 2015)(Elgzyri et al., 2014) (Smita et al., 2006) (Lydia et al., 2010).Foot problems in patients with diabetes are one of the most serious complications of diabetes mellitus and are a major public health issue in sub-Saharan Africa. Also is the commonest reason for hospitalization of patients with diabetes with prevalence as high as 25 % (Barrl et al, 2015) (Van schie, 2005) (Dinh, 2011).The pathophysiology of diabetic foot disease is multifactorial and includes neuropathy, infection, ischemia, and abnormal foot structure and biomechanics (Barrl et al, 2015).

Above all, the biomechanics of the diabetic foot are different from that of the non-diabetic foot. Fundamental changes occur in the overall gait with specific maladaptive processes occurring in the diabetic foot (Kim, 2011). Diabetic complications in the lower extremity are common and diverse. These complications result from complex interactions between diabetic vasculopathy, neuropathy, structural deformity and decreased immunity.

1.2 STATEMENT OF THE PROBLEM

Foot problems in diabetic patients are a major public health issue as well as the commonest reason for hospitalization for diabetic patients. The prevalence of diabetes is gradually increasing everywhere, most markedly in the world's middle-income countries.

Diabetic foot disease occurs in all types of diabetes showing higher prevalence among males and in patients more than 60 years old (Amin et al, 2016). According to WHO global reports in 2016, diabetes appears to intensely increase the risk of lower extremity amputation because of infected, non-healing foot ulcers. The rate of amputation in diabetic over non-diabetics is 1.5 to 3.5 events per 1000 persons per year. In low- or middle-income countries no such data estimates exist (WHO, 2016).

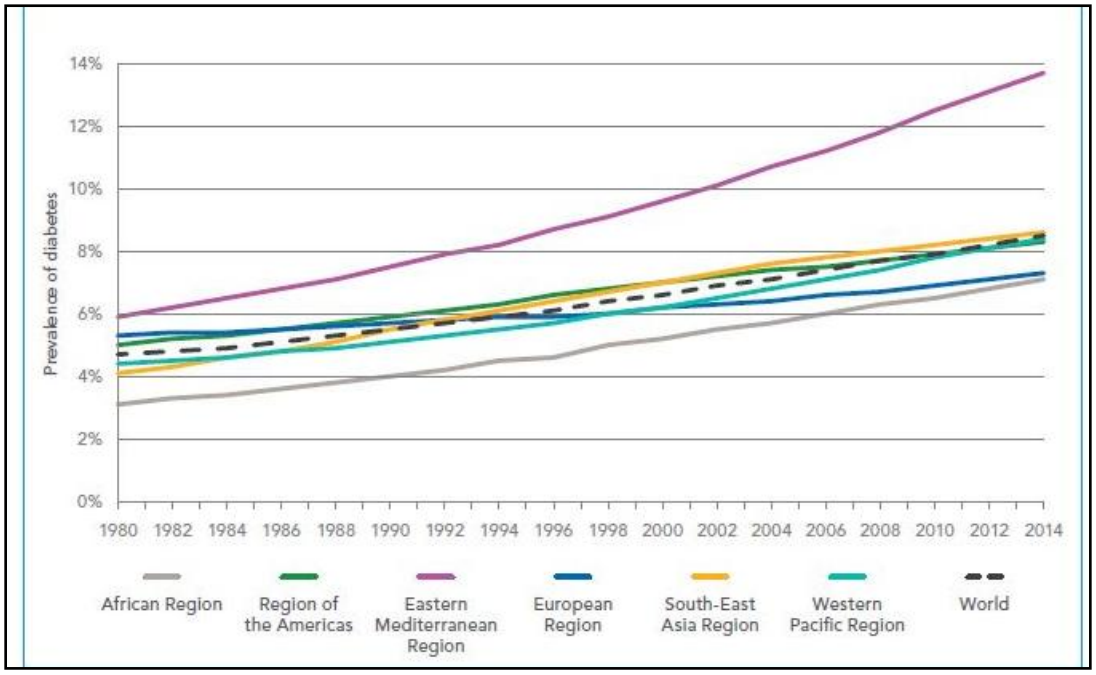

Figure 1: - Trends in prevalence of diabetics, 1980-2014, by WHO region.

Moreover, foot disorders, Ulceration, infection, gangrene, and amputation are significant complications of diabetes; of this, not all of these foot complications can be prevented, though those underline cause biomechanical alterations and maladaptive to diabetic foot(Kim,

2011).Although an incorrect or delayed initial diagnosis may increase the risk of serious complications including permanent disability and amputations(Barr l et al, 2015)(Kim, 2011).

Therefore, managing the diabetic foot is a complex clinical problem requiring a multidisciplinary collaboration of health care workers to achieve limb salvage. So, Appropriate biomechanical examination and early identification of biomechanical faults is an important component in the overall care of the diabetic foot. A thorough physical and radiographic examination of joint relationships is critical in identifying potential problem areas (Barr l et al, 2015)(Van schie, 2005)(Kim, 2011). Understanding foot biomechanics is an important component in the evaluation of diabetic foot. To this the researcher gets a discrepancy in (1) Lack of diabetes clinic in major hospitals, (2) there was no any biomechanical assessment format is used by medical practitioners, and (3) lack of awareness of both medical professionals and diabetic individuals explain the poor education of diabetic foot patients on what to do and how to manage the situation (Dinh, 2011). Also, the researcher bothered because there was no any kind of research was conducted regarding the case. Thus, the researcher was initiated to investigate a potential problem in the overall care of diabetic foot causes and believes an investigation of the case may fill the gap and used as a baseline to conduct further study as well as to ensure the quality of diabetic patient's life.

1.3. SIGNIFICANCE OF THE STUDY

The importance of this study is multiple, which may include:

I. Assess and compare biomechanical foot change in individuals with diabetes mellitus type-1 and type-2

II. Providing valuable information regarding the potential challenges of patients in early detection & prevention of possible diabetic foot complication

III. used as an insight for the concerned body

- ✓ To improve both quality of life & treatment approaches.
- ✓ To enhance awareness of health care provider & diabetic patient
- ✓ Opening doors for further studies to be carried out on in the same and/or related condition

2. LITERATURE REVIEW

2.1 Epidemiology

Approximately one out of eleven adults, equating to 415 million people worldwide, have diagnosed or undiagnosed Diabetes Mellitus (DM), (DiLiberto FE, et al.)With its escalating prevalence and incidence, has emerged as a significant health problem. (Smita R, et al., 2006)A WHO statistics estimating a rise in current diabetes diagnoses of nearly 50% across Europe since 2000are of particular concern for health services (Shavelson et al., 2011). And also by another WHO report in year 2011 diabetes people more than 300 million people suffered from diabetes mellitus (Wang, 2014).

It was estimated that the number of people suffer from DM would keep increasing & become the 7th leading cause of death in the year 2030 (Wang, 2014). The total number of people with diabetes is projected to raise from 382 million adults in 2013 to 592 million adults by 2035 (Bowling et al., 2015)(Elgzyri T, et al, 2014).

The consequences of diabetes for the human body are initiated at a molecular and cellular level, which promotes the widespread dissemination of cell dysfunction (Bowling et al., 2015)**.** In a recent survey, around 2.8% of all diabetic subjects had diabetic foot problems. Non-traumatic lower limb amputation is 86 times more common in subject with diabetes than age matched general population and almost all of them are due to diabetic foot problems (Wang, 2014). In another study Global prevalence of diabetic foot is 6.3%, and the prevalence in North America, Asia, Europe, Africa and Oceania was 13.0%, 5.5%, 5.1%, 7.2%, and 3.0% (Pengzi Zhang et al., 2017).

A study conducted across Africa showed that an estimated 14.2 million adults aged 20-79 have diabetes in the Africa Region, representing a regional prevalence of 2.1-6.7%.The majority (58.8%) of people with diabetes live in cities, even though the population in the region is predominantly (61.3%) rural. Diabetes in adults is in general much higher on islands in the Africa Region, compared to the mainland. The highest prevalence is found in the Seychelles 17.4%, followed by the island of Reunion 15.8%and Comoros 9.9%. Some of Africa's most populous countries have the highest numbers of people with diabetes, including South Africa 2.3 million, Democratic Republic of Congo 1.8 million, Nigeria 1.6 million and Ethiopia 1.3 million.

Nearly half of all adults with diabetes in the region live in these four countries (Abbas ZG et al., 2005).

2.2 Predictive Risk factor

Diabetic foot complication is result from complex interactions between diabetic vasculopathy, neuropathy, structural deformity and decreased immunity (Naidoo P et al., 2015). The diabetic foot is characterized by infection, ulceration and/or destruction of deep tissue in the foot, and is usually associated with neurological abnormalities and varying degrees of peripheral vascular disease in the lower limb (Foot, 2015). The foot is considered at-risk when any of the following is present: neuropathy, PAD, ulcer, deformity, loss of joint mobility, callus (Elgzyri T, et al, 2014).

Diabetic peripheral neuropathy (DPN)

Diabetic peripheral neuropathy (DPN), is a 'symmetrical, length-dependent sensorimotor polyneuropathy attributable to metabolic and microvessel alterations resulting in dysfunction affecting the sensory, motor, and autonomic nervous systems. The etiology and pathogenesis of DPN at all stages are resulted from the involvement of both vascular factors and metabolic factors that result in ischemic nerve injury (Lipsky, 2015) (Boulton, 2010).

DPN is one of the leading causative factors for altering biomechanical loading of the feet, together with foot deformity and limited joint mobility. DPN leads to an insensitive foot deficit and is believed to cause changes in foot function and structure as well as dryness of the skin, which can lead to the excessive callus formation. Patients who lost sensation in their feet often sustain puncture wounds, friction wounds and burns that can become infected and/or ulcerated and lead to amputation (Bowling, 2015) (Lipsky, 2015) (Boulton, 2010).

Peripheral neuropathy is the most common neuropathy syndrome seen in persons with diabetes, occurring in 5–80% of diabetes patients. The prevalence of neuropathy increased with age, duration of diabetes, presence of microvascular complications, and poor glycemic control.

A study conducted across Africa has shown that a wide range in the occurrence of peripheral neuropathy, ranging from 25% in Tanzania, 4% in Zimbabwe, 84% in Algeria, 61% in Zambia

and 37% in Sudan (Ramachandran, 2004)(Guidance, 2015). In another comparative, multi-centric study in Soest, Germany, Dares Salaam, Tanzania and Chennai, India, showed that PN was a common condition associated with diabetic foot lesions in all the centers (79%, 84% and 80% respectively).

In another study conducted in the UK among recruited 6487 patients from 118 hospitals to investigate the prevalence of peripheral neuropathy in the diabetes population. Of these, the overall prevalence of DPN was 28.5% (95% confidence interval 27.9%-29.6%) with the Prevalence was significantly higher in type II diabetes (32.1%) than in type 1 diabetes (22.7%) (Bowling, 2015).

The most common form of clinical neuropathy, distal symmetric sensorimotor polyneuropathy, affects up to 50% of people who have had diabetes >15years and affects the motor and sensory modalities in a "stocking-glove" pattern. Autonomic neuropathy frequently develops concurrently.

Peripheral neuropathy is associated with an 8-to18-fold higher risk of ulceration and a 2-to15-fold higher risk of amputation. Peripheral neuropathy is thought to be the underlying pathophysiological alteration leading to Charcotarthropathy. The increased risk for these adverse outcomes is imparted through several different mechanisms

Peripheral arterial disease (PAD)

Peripheral arterial disease significantly and independently developed as a result of DM.

Peripheral arterial disease, generally caused by accelerating atherosclerosis of the peripheral blood vessels, and is an important risk factor for impaired wound healing and lower extremity amputation. Diabetes-related peripheral artery disease may also display characteristic micro aneurysms and tortuosity in distal arteries (Lipsky, 2015) (Naidoo et al., 2015).Lower limb atherosclerosis in patients with diabetes tends to occur more distally. Peripheral vascular disease, defined as at least one absent pulse, was noted in15% of people at 10years and 45% of people at 20 years after diagnosis of diabetes. Arteries below the knee are preferentially affected, particularly the peroneal and posterior tibial arteries (Melton LJ III et al.).

In study conducted in Germany, Tanzania, and India, showed that PVD was showed 48%, 14%, and 13% respectively (Ramachandran, 2004). In another study the rates of PVD in Tanzania

have increased from 2.9% in 1980 to 12.5% in 1997 and 21% in 2002; similar rates in Nigeria have increased from 1.7% in 1968 to 4.4% in 1971 and 54% in 1990 (Abbas ZG et al., 2007).

Approximately 3–4% of individuals with diabetes have foot ulcers or deep infections and 15% develop foot ulcers during their lifetime. The risk of lower extremity amputation increases by a factor of 8 once an ulcer develops (Naeem Ashraf et al., 2011).

Altered biomechanics

An increased risk of ulceration and amputation has been associated with alterations in the normal biomechanics of the foot, including increased plantar pressure, bony abnormalities, and limited joint mobility. Increased plantar pressure has been associated with recent or current ulcers and with risk of amputation. The causes of the increased plantar pressure in diabetic people include increased body mass, structural alterations of the bone and connective tissue, limited joint mobility, changes in skin and callus formation, and changes in posture and gait. Increased plantar pressure is often noted in the presence of bony deformities. Up to half of all people with diabetes have a hammer toe or claw toe deformity created by motor neuropathy, which causes atrophy of the interosseous and lumbricals muscles.

2.3 Complications

Diabetic complications in the lower extremity are common and diverse. They are associated with significant morbidity and mortality and impact heavily upon the public health system. In 2013, DM-related complications were a major cause of disability and reduced quality of life, and an estimated 5 million people aged 20–79 years worldwide died prematurely from the disease (M. Gizaw et al., 2015).

A retrospective study in India, Diabetic foot accounted for 6.95% of total surgeries done. Of this 39 (86.66%) patients had type I diabetic foot complications (14 (31.1%) had Wet gangrene, 19 (42.2%) had Abscess, 4 (8.89%) had Necrotizing fasciitis and 2 (4.44%) had Cellulitis whereas 1 (2.2%) patients had type II diabetic foot complications (Jain AKC et al., 2013).

A cross-sectional survey study conducted in Taiwan, for a total of 12, 531 case subjects Diabetic foot problems were present in 369 patients with 540 initiating events. Ulcers represented 86.7%

of all initiating events. Approximately 26.9% of the ulcers progressed to gangrene or amputation, and ulcers preceded 71.9% of all amputations (TSENG, 2003).

In another cross-sectional survey carried in the UAE from 513 diabetic patients 68 (13.6%) had Type I DM and 431 (86.4%) had type II DM; of this 199 (39%) had Peripheral Neuropathy and 59 (12%) had Peripheral Vascular Disease (Fatma Al-Maskari et al., 2007).

A cross-sectional cohort study in Saudi Arabia showed among 62,681 diabetic patients 54,669 (95.45%) patients had Type-II diabetes [Of this 1942 (94.27%) had foot ulcer, 118 (6.08%) had gangrene and 634 (32.65%) of them was with amputation] while 2604 (4.55%) was presented with Type-I diabetes [Of this 118 (5.73%) had foot ulcer, 1 (0.85%) had gangrene and 30 (25.42%) of them was with amputation] (Al-Rubeaan K et al., 2015).

A descriptive retrospective study done in Ethiopia showed that, from a total of 523 DM patients301 (72%) patients had type II DM (of this 119 (39%) had Diabetic foot ulcer or gangrene, 111 (17%) had a diabetic foot infection, 89 (14%) had Diabetic neuropathy) and 104 (28%) type I disease (of this 7 (7%) had Diabetic foot ulcer or gangrene, 9 (11%) had a diabetic foot infection, 16 (20%) had Diabetic neuropathy) (M. Gizaw et al., 2015).

Some of the biomechanical alterations common to the diabetic foot are (Naidoo et al., 2015) (Donna, 2013) (Strolli, 2015).

Diabetic foot ulceration (DFU)

Ulceration is generally defined as a breakdown in the skin that may extend to involve the subcutaneous tissue or even to the level of muscle or bone (Boulton, 2010) (Angela et.al, 2015). Diabetic foot ulcers are a complex problem that leads to foot infection, necrosis and most of the time results in major amputation. Diabetic foot ulceration occurs as a consequence of the interaction of several contributory factors, such as: Peripheral neuropathy (sensorimotor), trauma (poor footwear, walking barefoot, falls/accidents), biomechanics (limited joint mobility, foot deformity, bony prominence, callus), PVD (Boulton, 2010) (Angela et.al, 2015).

Foot ulcer affects one of six diabetic patients during the course of their disease. Furthermore, approximately 20% of diabetic patients with foot ulcers also have underlying osteomyelitis, whereby the forefoot (metatarsal head and distally) is the involved site in 90% of cases. The

average onset of foot ulceration in diabetic patients is about 14 years after the initial diagnosis of diabetes mellitus and the amputation rate in western countries is 2.5-6 per 1000 patients per year (Nina Troskot et al., 2013). Finally, economic costs of treating foot ulcers in patients with diabetes mellitus are enormous.

Approximately 3–4% of individuals with diabetes have foot ulcers or deep infections and 15% develop foot ulcers during their lifetime. The risk of lower extremity amputation increases by a factor of 8 once an ulcer develops (Naeem Ashraf et al., 2011). Diabetics as opposed to non-diabetics also have a 15- to 46-fold greater risk of lower extremity amputation and 20- to 50-fold greater risk of gangrene (Nina Troskot et al., 2013)**.**

DFU may become more common in clinical practice in the tropics with the increasing prevalence of diabetes in the Nigerian and Ghanaian adult populations. The lifetime risk of a person with diabetes developing a foot ulcer could be as high as 25%, and it is believed that every 30 seconds a lower limb is lost somewhere in the world as a consequence of diabetes. In Nigeria the mean costs of successfully treating a patient with Diabetes Mellitus Foot ulceration are 181581.00 Nigerian Naira, which approximately equivalent to 1200 US dollars, this amount is unaffordable by most hospital patients as about 60% of the population live below the poverty line (O.O. Desalu et al., june 2011)**.**

Deformities and limited joint mobility

Foot deformities and limited joint mobility of the ankle and foot make the foot susceptible to abnormal areas of concentrated high pressures, restrict the foot's ability to absorb shock, and increase the risk of ulceration. Hence, common deformities in patients with diabetes include hammer toes, claw toes, prominent metatarsal heads, and Hallux valgus. These deformities makes the biomechanics of the foot is more severely affected, and make the plantar metatarsal heads and dorsal aspect of the toes vulnerable to excessive pressures and repetitive trauma (Oscar et al., 2015).

Wet gangrene

Gangrene is a form of tissue necrosis with added putrefaction. Wet gangrene of the foot is one of the characteristic lesions seen in diabetes and is sometimes called "Diabetic gangrene". This type

of gangrene develops rapidly and is almost painless because of the associated neuropathy. Wet gangrene is believed to develop from thrombosis of the small vessels due to infection. The affected part is soft, swollen, putrid, necrotic, and darkened to black color. The affected part (i.e., digit or toe) is engorged with blood, which favors the rapid growth of putrefactive bacteria.

Abscesses

Abscess in the diabetic foot can occur either on the dorsum or on the plantar aspect of the foot. Abscesses can also develop in the nail fold area (i.e, paronychia) and web spaces. Besides, the entry of infection, especially on the plantar aspect, is usually from a trauma like a nail puncture or foreign body injury that occurs in neuropathic feet. The insensitivity allows such injury to go unrecognized.

Infections in the web spaces are insidious due to poor foot hygiene to accumulation of moist detritus, or fungal infection in the interdigital web spaces. Web space abscesses are dangerous because of the proximity to the digital vessels. On the plantar aspect of the foot, the central space is most commonly involved as compared to the medial or lateral space abscesses. Many times the web spaces, or the central space infection, can cause thrombosis of the vessels leading to digital gangrene.

Necrotizing fasciitis

Necrotizing fasciitis is a severe form of a soft tissue infection involving the superficial and deep fascia. This disease spreads rapidly and can involve the whole limb within hours. Also, in necrotizing fasciitis, the infection starts at the level of the subcutaneous fat and deep fascia. Rapidly spreading erythema, edema, and severe pain are characteristics of necrotizing fasciitis. Extensive skin and facial necrosis, and gray malodorous fluid referred to as “dishwater pus”, characterize necrotizing fasciitis.

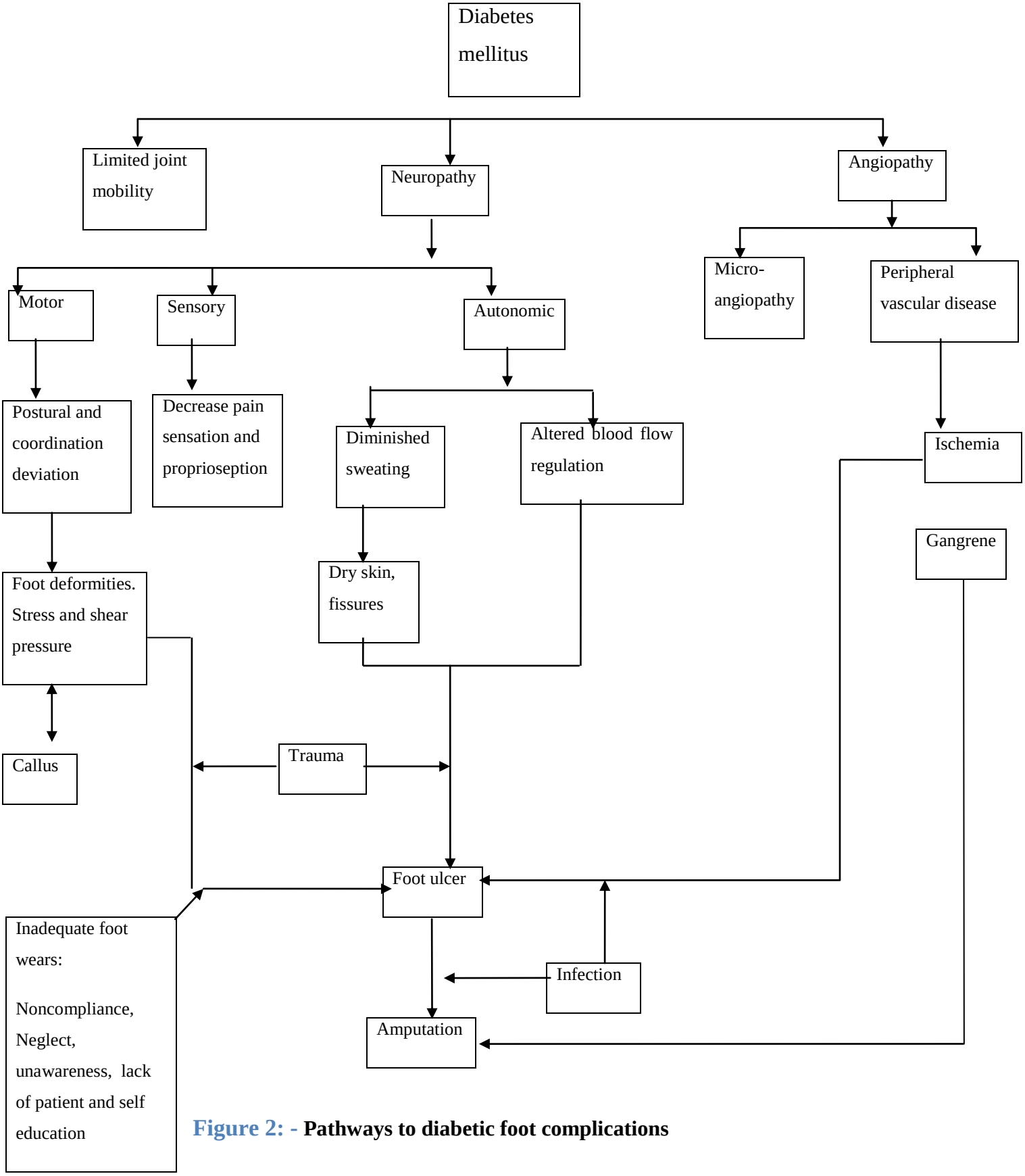

Figure 2: - Pathways to diabetic foot complications

3. OBJECTIVES

3.1 General Objective

The general objective of the study was:

- ✓ To compare Anatomical and mechanical foot change in individuals with type-1 and type-2 diabetes mellitus among diabetic individual who have been on follow up in Mizan-Tepi teaching hospital, Bench Sheko zone, Mizan-Aman Ethiopia, 2019 G.C.

3.2 Specific Objectives

- ✓ To assess Anatomical and mechanical foot change in individuals with type-1 and type-2 diabetes mellitus
- ✓ To compare Anatomical and mechanical foot change in individuals with type-1 and type-2 diabetes mellitus
- ✓ To describe the knowledge and practice of foot care in individuals with type-1 and type-2 diabetes mellitus

4. MATERIALS and METHODS

4.1 Study Design

- Institution-based cross-sectional comparative, descriptive study design was implemented.

4.2 Study Period

- The Study was conducted from May 2019- November 2019 G.C

4.3 Study Area

- This study was conducted in Mizan-Aman; the capital city of Benchi-sheko zone which is one of the 17 zones in SNNPRs located 561 km away from Addis Ababa, the capital city of Ethiopia, in the Southwest part of the country, whose population number is 829,493.The zone includes a city administration (Mizan-Aman), 10 Woredas (districts), 246 kebeles (smallest administrative units) (229 rural and 17 urban). There is one teaching Hospital (Mizan-Tepi University teaching Hospital). The zone has about 40 functional health centers and five under construction (Koka, Aroge birhan, Gabisa, Zozo and Kuju). Additionally, there are one University and one Health sciences college.

4.4 Source population

- All diabetic patients who already have follow-up in Mizan-Tapi University Teaching Hospital.

4.5 Study Population

- Sampled individual who are already diagnosed as Diabetic and came to Mizan-Tapi University Teaching Hospital chronic out-patient department during the study period.

4.6 Sample Size

- The sample size (n) of the patients was determined by drawing p-value from the previous studies.

- The desired sample was calculated by using DOUBLE POPULATION PROPORTION COMPARATIVE formula for unequal sample

$$n_1 = \frac{\left[Z_{\alpha/2}\sqrt{\bar{p}\bar{q}\,(1+1/\lambda)} + Z_{\beta}\sqrt{p_1q_1+p_2q_2/\lambda}\right]^2}{\Delta^2}$$

Where $n_2=n_1\lambda$, $\bar{p} = (p_1+\lambda p_2)/(1+\lambda)$

r = Ratio of Type IDM and Type II DM = 1:2

$Z_\beta = 0.84$ for 80% power

$Z\,\alpha/2 = 1.96$ for 95% confidence level

Δ= hypothesized difference of interest= |P2-P1|

p1=0.1, p2=0.44, $\bar{P}$ = (0.1+2*0.4) /(1+2) = 0.3

q1=0.9, q2=0.66, Δ = 0.44-0.1 = 0.34

Therefore, $n_1 = \frac{(1.96\sqrt{0.3*0\quad(7(1+1/2)} + 0.8\quad\overline{(\sqrt{(0.1*0.9+0.44*\,0.66)}^2}}{1\qquad(0.34)^2}$

$n_1 = 98$

n2=2*n1=2*98=196

So, totally the sample will be **294**

4.7 Inclusion and Exclusion criteria

4.7.1 Inclusion criteria

1) All patients with DM (type 1 or type 2)
2) All patients aged above 18 years with the diagnosis of DM (type 1 or type 2)
3) Patients willing to provide voluntary written consent for participation in the study.

4.7.2 Exclusion criteria

1) All patients aged below 18 years
2) Non-diabetes related orthopedic foot problem
3) Patients and/or his/her legally acceptable representative not willing to provide voluntary written consent for participation in the study.

4.8 Data Collection Procedures

After getting consent from selected subjects, data were collected through a structured questionnaires and clinical assessments. The questionnaire has different parts including; socio-demographic data (age, sex, occupation, education, family history of DM), Clinical data (blood glucose level, blood pressure value, BMI and physical measurements), and participants foot knowledge & level of practice regarding foot care. The whole data collection procedure was performed by the principal investigator and Medical doctor. The study participants were checked whether or not they fulfill the inclusion criteria. A participant was instructed about what the items meant and how they could respond to them**.**

Questionnaires were divided into 4parts,1st parts contain information about socio-demographic profile, 2nd parts contain clinical profile, 3rd part contain inspection and assessment and 4th part contain participants' knowledge about diabetic foot complication, their attitude and practice regarding diabetic foot care.

Demographic and Behavioral Information

After receiving informed consent, diabetic patients were interviewed by their treating doctors about DM type, duration, treatment profile, level of control, presence or absence of chronic DM complications, including previous ulcer/amputation of the lower limbs and the presence of vascular symptoms of cramps and/or claudications, neuropathy symptoms of tingling, numbness, and burning sensation with a 'stocking and glove' distribution.

Physical Measurements

Fasting blood samples that were taken to assess blood glucose levels were classified into the following groups: before meal 4-7mmol/L for both type-1 & type-2 or after meal under 9mmol/L for type-1 & under 8.5 mmol/L type-2 is **normal**, <3.8 mmol/L **Hypoglycemic**, and > 11.1 mmol/L **Hyperglycemic** (NICE, 2019). Height was measured without shoes by using Stadiometer. Body weight was measured while wearing light clothes by an adjusted scale. Bodymass index (BMI) was calculated by the formula: weight in kilograms divided by height in meters squared (weight in Kg, divided by the square of the height in m^2). BMI

defined <18.5kg/m^2**underweight**, 18.5-24.9 kg/m^2**normal**, 25-29.9 kg/m^2**overweight** and >30 kg/m2 **obesity** (WHO, 2016).

Blood pressure (BP) was measured by using sphygmomanometer in sitting position for both arms (right and left) and in lying position for either of the foot at dorsalispedis and posterior tibial artery. Ankle-brachial index (ABI) was calculated by the formula: - the highest systolic blood pressure of the leg (Ankle) divided by the higher of the two brachium measurements (ABI= PsL/PsB). ABI classify as if the ratio is between 0.90-1.30 **Normal**, between 0.70-0.90 **mild**, between 0.40-0.69 **moderate**, and <0.40 **severe** (Hopkins, 2016).

Other information that was documented included the type of diabetic foot problems (claws/hammer toes, halux valgus, pes cavus, limited joint mobility, calus, ulceration, edema, infection). Skin status (color & cracking) and nail status (color, trophic changes) were also noted.

Peripheral Neuropathy was assessed by vibratory, muscle strength and tendon reflex testing. Pressure, pain, vibration and joint position sensitivities were evaluated bilaterally. For pressure perception, the neurotips was used on 4 sites on the foot. These sites were without callus, notably the pulps of the Hallux and metatarsal heads off first, third and fifth toes. The site was considered sensate if the patient responded, "Yes" upon contact with the neurotips in all of the four sites of the foot and insensate if there was “No” response in one of the four sites of the foot. For vibration perception, a 128 Hz tuning fork was applied at 3 sites on the foot, the pulp of the Hallux, the lateral and the medial malleoli. The patient was asked to describe what he/she felt. If he/she described a feeling of vibrations in the pulpe of the hallux, the site concerned was considered normal. If he/she described anything other than vibrations, the site concerned was considered abnormal (Jennifer A. Mayfield et al., 1998). In addition, pinprick perception (using standard neurotips) on the dorsal surface of the great toe and the index finger was evaluated. Neuropathy was further assessed by examining the tendon reflexes bilaterally and testing for muscle strength by examining for extension of the knee and dorsiflexion of the foot (Zaid Abu-Qamar et al., 2012).

Lower limb ischemia was ascertained by the examining physician through palpation of the dorsalispedis and the tibialis posterior pulses when one or more foot pulses were judged absent

with or without symptoms of lower-limb claudication and/or amputation or gangrene were present.

Knowledge and practice of diabetic foot care.

Patients were interviewed by their physician by structured questionnaire to assess the knowledge and practice of diabetic foot care. The questionnaire was developed from the literature on foot care and The Diabetes Committee of the American Orthopedic Foot and Ankle Society guidelines.

4.9 Study variables

4.9.1 Dependent variables

- Diabetic foot

4.9.2 Independent variable

- Age
- Sex
- Gait
- Footwear
- Trauma
- Disease condition (vasculopathy, neuropathy, microvascular complications)
- Socioeconomic status
- Patients' knowledge
- Lifestyle (Normal, sedentary)
- Anatomic structural change (in foot)

4.10 Operational definition

a. **Biomechanics**-is the application of mechanical laws to the musculoskeletal system and locomotion to governing structure, function, and position of the human body.
b. **Diabetic foot-** is a foot that exhibits any pathology that results directly from diabetes mellitus or any long-term (or "chronic") complication of diabetes mellitus.

c. **Foot deformity: -** abnormalities in the shape of the toes, arches, or bottoms of the feet.

d. **Foot care education: -** the process of giving systematic instruction in all aspects of preventive and corrective care of the foot and ankle for diabetic patients.

e. **Claw\ hammer toes: -** the plantar flexion the distal and middle interphalangeal joint in comparison with proximal phalanx is called hammer toe while claw toe was defined as the dorsal flexion of the metatarsophalangeal joint associated with hammer toe.

f. **Hallux valgus:-** A deformity of the grater toe by abduction valgus and pronation associated with bone prominence on the inner edge for the metatarsal (bunion).

g. **Pes Cavus: -** An abnormally high medial longitudinal arch, which extends between the first metatarsal head and the calcaneus.

h. **Callus:-** Localized hyperplasia of the startum corneum of the epidermis.

4.11 Standard definition

i. **Diabetes mellitus**-chronic disease that occurs either when the pancreas does not produce enough insulin (a hormone that regulates blood sugar, or glucose), or when the body cannot effectively use the insulin

ii. **Patients -** individuals who diagnosed diabetes & treated at the DM center

4.12 Data Analysis

- Consistency and completeness of each questionnaire were checked throughout the data collection, data entry and analysis. Data was coded and entered using Excel spreadsheets, was cleaned & treated using SPSS version 24. Descriptive analysis was used to determine the frequency, percentage table and graph was used. Results were presented as tables and graphs together with brief descriptions.

4.13 Ethical consideration

- Permission to conduct this study was obtained from Department Research Ethics Review Committee (DRERC). The consent of the respondents was asked and the right to refuse to respond to any of the questions or refusal of participation was respected.

Finally, confidentiality and privacy of the information was maintained by avoiding patient's name.

4.14 Data Quality Assurance

- First, to make the quality of the data structured questionnaire was used. Then, prior to data collection, pre-test was conducted among 5% of sampled study participants in the study area. Amendments and modifications to the items were made based on the obtaining feedback.
- Data was collected by principal investigator and by one medical doctor using structured questionnaires and diabetes assessment checklist format by principal data collectors. Finally, the collected data was cross checked for its completeness, clarity and consistency.

4.15 Dissemination of the Result

- The result of this research will be disseminated to, AAU department of Anatomy, Ministry of Health, Addis Ababa Health bureau and other stakeholders and policy makers.

5. Result

Socio-Demographic Characteristics of the Study

A total of 294 participants with diabetes participated within the study, of whim 178 (60.5%) were males and 116 (39.5%) were females. (**Table 1**) Their mean age was 43±14. 5 Years.

Table 1: Age distribution of study patients (n=294), MTUTH, June 1st to November 30st 2019 G.C.

	Median age	Minimum	Maximum
Entire group	43 Years	18 Years	79 Years
Male	43 Years	18 Years	74 Years
Female	42 Years	18 Years	79 Years

From 294 participants, 196(66.7%) of them was T2DM [126 (64.3%) of them ware male and 70 (35.7%) were female] and 98 of them was T1DM [52 (53%) of them ware male and 46 (47%) were female] as shown in **figure** 1.

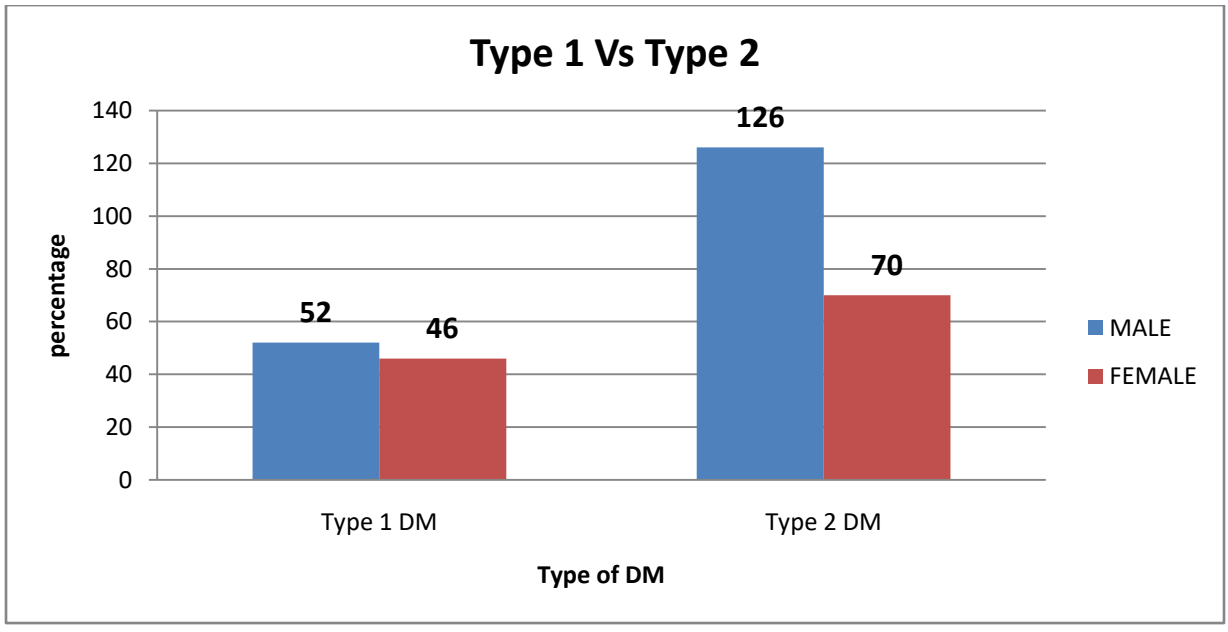

Figure 1: - Prevalence of diabetes in study participants, MTUTH, June 1st to November 30st 2019 G.C.

The present finding showed that from the whole participants, 63.2% were Illiterate, followed by 19.4%, 11.6%, 5.8% of primary, secondary, and university graduates, respectively. The majority

of the study participants, 34.7% (102) of them were physically active, 23.8% (70) were smokers and 18.9% (74) were alcohol drinker.

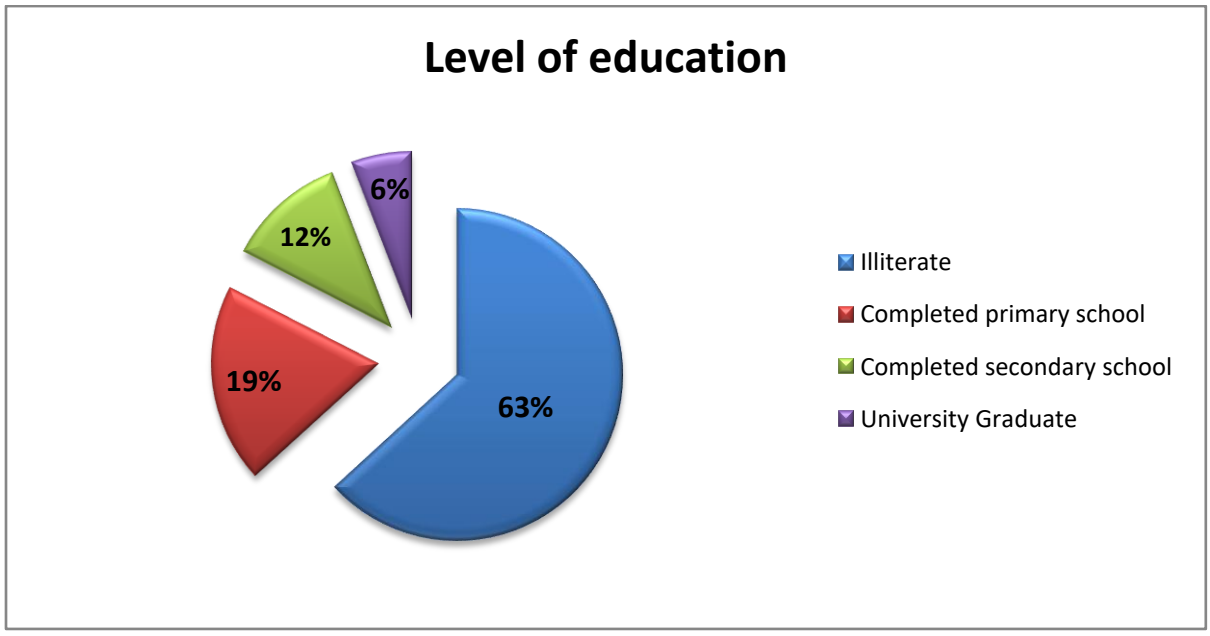

Figure 2: - Level of education in study participants, MTUTH, June 1st to November 30st 2019 G.C.

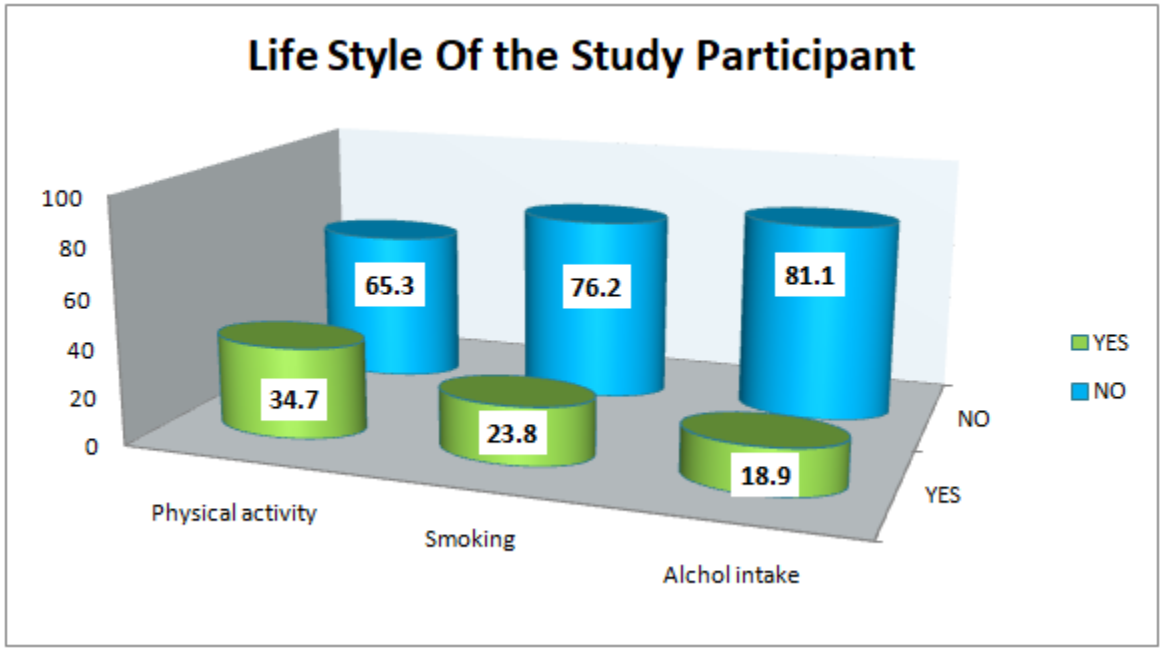

Figure 3: -Lifestyle of the study participant, MTUTH, June 1st to November 30st 2019 G.C.

Clinical Characteristics

From all participants, 63.9% were normal weighted, 31.3% were obese or overweighed and 4.8% were under weighted. One hindered fourteen (38.8%) participant had been diagnosed DM in the past 1-5 years, nineteen-nine (33.7%) in the past 6-10 years, fifty-eight (19.7%) in the past 11-20 years and twenty-three (7.8%) in the past more than 21 years **(Table 2).**

Table 2: Clinical Characteristics of study participants (n = 294), MTUTH, June 1st to November 30st 2019 G.C.

		Prevalence of DM	
		N	**Frequency (%)**
Duration of the disease	1–5 years	114	38.8
	6–10 years	99	33.7
	11–20 years	58	19.7
	>21 years	23	7.8
BMI	Underweight (<18.5)	14	4.8
	Healthy weight (18.5–24.99)	188	63.9
	Overweight and Obese (>25)	92	31.3
Blood glucose level	<140mg/dL (<7.7mmol/L)	202	68.7
	>140mg/dL (>7.7mmol/L)	92	31.3

Prevalence of Foot Complications

The prevalence of foot deformities among the study participants is presented in table 3. The overall prevalence of foot deformities was 46.5%. the most frequent deformities was claw/hammer tow which was preset in 15% (3% in Type-1 and 12% in Type-2) participants and the lowest prevalence were for pes cavus which were present in only 8.2% of the participants (1.2% inType-1 and 7% in Type-2).

Table 3: Prevalence's of foot deformities in the study participant, MTUTH, June 1st to November 30st 2019 G.C.

Rank	Foot deformity	N		Prevalence (%)	
		Type-1	Type-2	Type-1	Type-2
1	Claw/hammer toe	9	35	3%	12%
2	Hallux valgus	11	25	3.8%	8.5%
3	Callus	6	26	2%	9%
4	Pes cavus (High medial arch)	4	20	1.2%	7%

As per **figure** 4, from the total participants 52 (32.6%) participant has diabetic peripheral neuropathy (12.2% in Type-1 DM and 20.4% in Type-2), 25.5% has peripheral arterial disease (7.1% in Type-1 and 18.4% in Type-2), and 55.1% have diabetic foot ulceration (10.2% in Type-1 DM and 44.9% in Type-2). Most (95%) participants only visited diabetic clinic for their treatment, and 91.8% visited the clinic monthly.

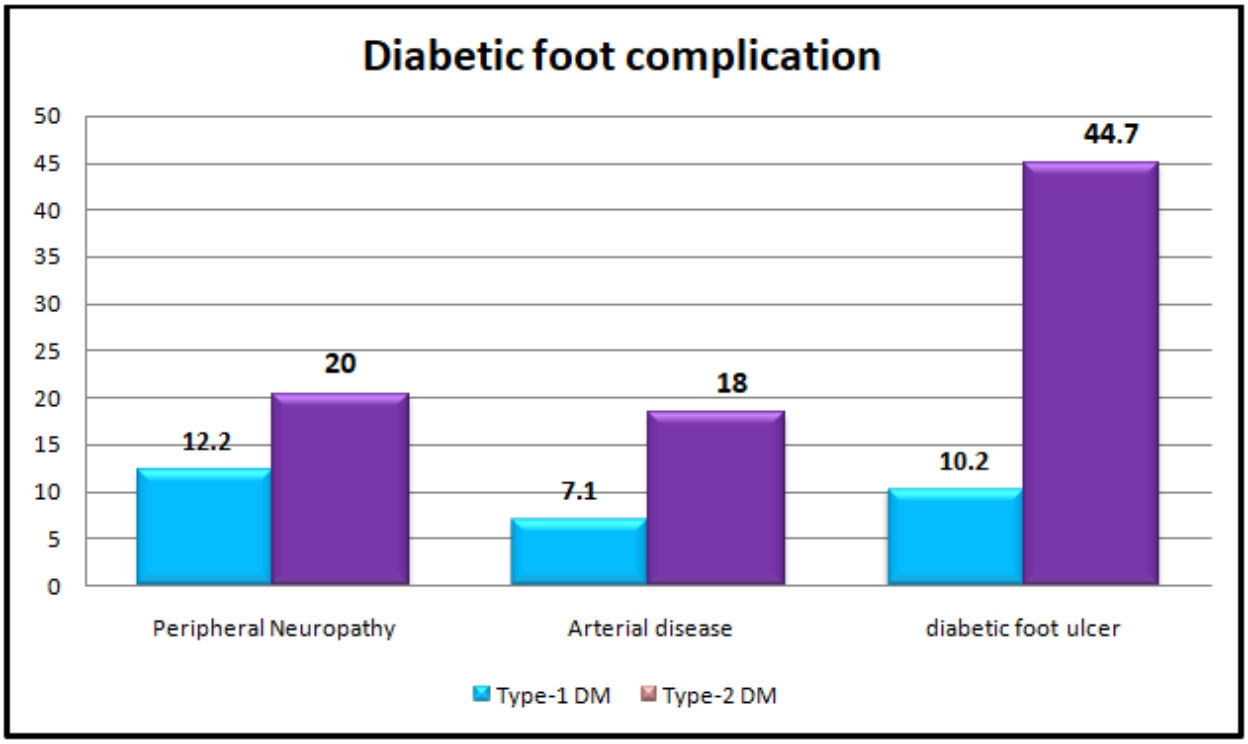

Figure 4: - prevalence of diabetic foot complications among Type-1 and Type-2DM patients, MTUTH, June 1st to November 30st 2019 G.C.

Diabetic foot education and level of practice

Around half (43.9%) of Type-1 DM and around one-third (18.4%) of Type-2 DM patients were understood the effects of diabetes on foot health. Only thirty-nine (39.8%) of Type-1 DM and thirty-one (15.8%) Type-2 diabetes participants were identified appropriate foot care practices. Considering the participants getting foot care knowledge, 10.2% were got by attending foot care class, 32.6% were getting from their health care provider and 29.6% were getting by reading handouts/leaflets in Type-1DM. meanwhile 7.7%, 20.4%, 11.2% in Type-2 DM respectively.

TABLE 4: Knowledge and attitudes about diabetic foot care and previous diabetic foot education in patients with DM type-1 and type-2 MTUTH, June 1st to November 30st 2019 G.C.

Knowledge and attitudes	**TYPE-1 DM**				**TYPE-2 DM**			
	YES		**NO**		**YES**		**NO**	
	N	**%**	**N**	**%**	**N**	**%**	**N**	**%**
Do you understand the effects of diabetes on foot health?	43	43.9	56	57.1	36	18.4	160	81.6
Can you identify appropriate foot care practices?	39	39.8	59	60.2	31	15.8	165	84.2
Have you ever attended a class on how to care for your feet?	10	10.2	88	89.8	15	7.7	181	92.3
Have you ever received education about foot care from your health care provider?	32	32.6	66	67.4	40	20.4	156	79.6
Have you ever read any handouts/leaflets on foot care/foot wear?	29	29.6	69	70.4	22	11.2	174	88.8

Figure 5 shows that around half (54.1%) of Type-1 DM and 51% type-2 DM patients cannot reach their feet for self care practice. Around 75% in type-2 DM and 46.9% in type-1 DM patients was not inspected their feet regularly. Also, 42.9% of type-1 and 65.3% type-2 DM participants were not examining their feet. Washing and drying of feet was present in 71.4% of type-1 and 37.9% of type-2 patients. However, only 33.7% of type-2 patients used oil or moisturizing for their feet, but in type-1 it was 68.3%.

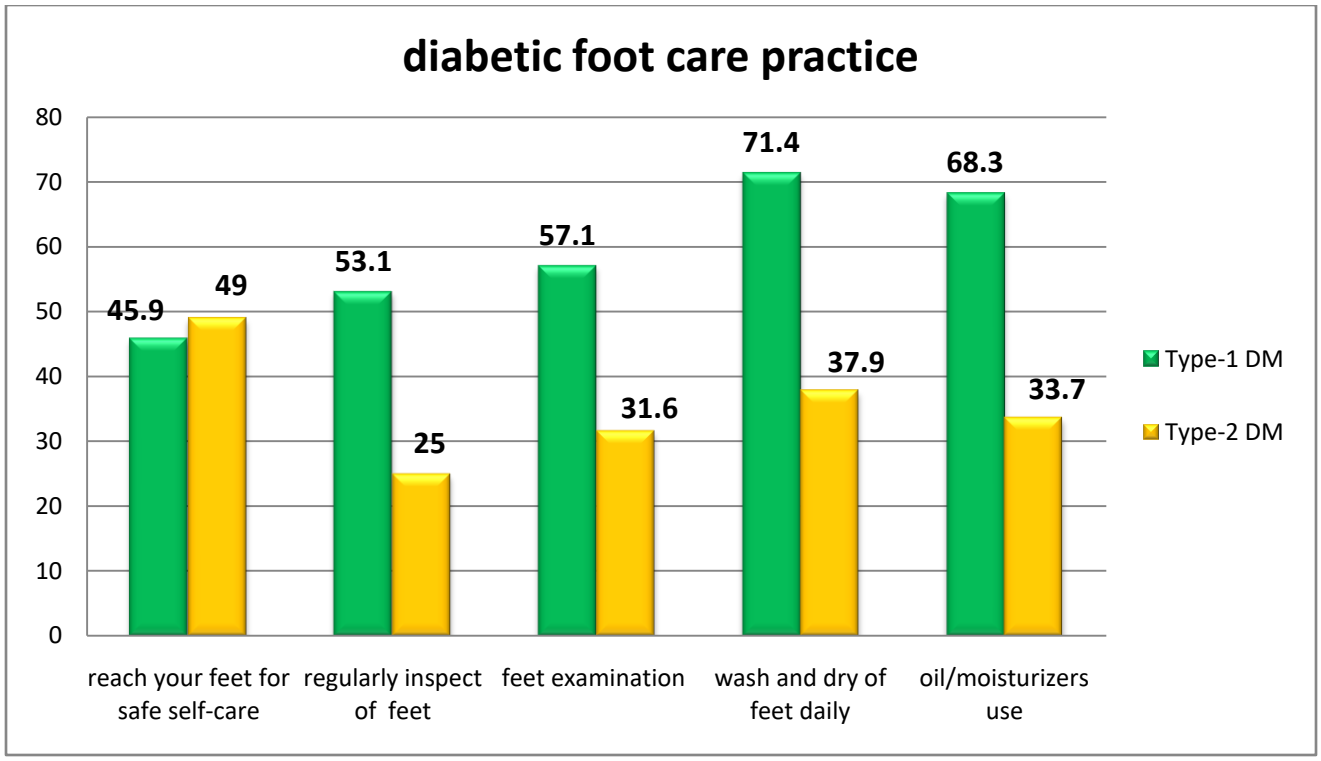

Figure 5: -Level of foot care practice among type-1 and Type-2 DM patients, MTUTH, June 1st to November 30st 2019 G.C.

6. Discussion

Normal gait outcomes from a complex interplay of neural, muscular and skeletal capabilities that are coordinated and supervised by the central nervous system. Change in foot posture and architecture as a result of the disorder, inclusive of diabetes, impact on the ordinary biomechanics of taking walks and weight bearing on the foot. Foot problems in patients with diabetes are one among the four most serious complications of diabetes. Moreover, diabetic foot is related to several commonly identifiable functional and structural foot deformities. These can also exist in isolation or aggregates and brings about a predisposition to several diabetes related foot complications. The key pathophysiological factors for diabetic associated foot complications are peripheral neuropathy, vasculopathy and foot deformities.

The diabetic foot is characterized by infection, ulceration and/or destruction of tissue deep within the foot, and is usually related to neurological abnormalities and varying degree of pheripheral vascular disease inside the lower limb (Lipsky et al., 2015). These complications result from complicated interaction between diabetic vasculopathy, neuropathy, structural deformity, lose of joint mobility and reduced immunity (Elgzyri et al., 2014) (Naidoo et al., 2015).

In the present study, 66.6% of the study participants were type-2 diabetes patients. DFU was found to be the commonest type of diabetes related to a foot complication followed by foot deformity, PN, PAD 55.1%, 46.5%, 32.6% and 25.5%, respectively. Most (95%) of the participants best visited the hospital for their treatment, and 91.8% of the participants' visited the medical institution monthly. This study is comparable with studies done in Black Lion Referral Hospital, Addis Ababa, Ethiopia, from a total of 523 diabetes patients 72% of the patients had type-2 diabetes; Among these 39% of the patients had DFU, 17% of the patients had diabetic foot infection, 14% of the patients had DPN; and 28% of the patients had type-1 diabetes; of the cases, 7% of the patients had DFU, 11% of the patients had a diabetic foot infection and 20% of the patients had DPN (Gizaw et al., 2015).

The prevalence of overall foot deformities was 46.5%. The most common structural foot deformities were claw\hammer toe (15%), Hallux valgus (12.3%), Callus (11%), and pes cavus (8.2%). The prevalence of foot deformities had been studied previously in different populations with variation in the prevalence of many of these deformities. Some of these studies showed a

lower prevalence than our findings (17-34%) (Bakri FG et al., 2012) (Ndip EA et al., 2006) While a clinical study conducted in UK (Walters et al.) which examined foot deformities (claw\hammer toe, Hallux valgus, pes cavus, and Callus) among people with diabetes found a prevalence of 44.5% the prevalence of such deformities are similar to our findings.

However, another study reported a higher prevalence of foot deformities 64% in (Anas Ababneh et al., 2019) 64.2% and (Helfand AE, 2004). Similarly, three studies had also estimated high prevalence of foot deformities ranged between 54.3 % - 79 % (Jones NJ et al., 2013) (Dòria M et al., 2016) (Kaminski M et al., 2012). This variation is due to age, presence of underlying health conditions, assessment procedure and poor glycemic control. In addition, because each type of foot deformities has its own prevalence and etiology, this can also lead to a variation in the prevalence outcomes.

Peripheral neuropathy is the most common neuropath syndrome seen in people with diabetes. The prevalence of PN in the literature is 5-80% of the case. In our study, the prevalence of PN was found in 32.6% (52 participants); 12.2% in type-1 diabetes and 20.4% in type-2 diabetes; of the cases, comparable to the percentage found in the studies of 37% (Ramachandran, 2004**),** and 28.5% (Bowling, 2015)but lower than in the studies of 79% and 84%(Ramachandran, 2004), and 80% (Zaid et al., 2012) this variations are due to lack of screening tool and number of the sample size. Also, may be due to relative increment in the number of patients who have diagnosed recently because complication is expected to increase as diagnosed year gap increased weather on treatment or not as different studies showed.

Peripheral arterial disease (PAD) is a condition characterized by way of atherosclerotic occlusive disorder of the lower extremities. PAD normally caused by accelerating atherosclerosis, and is a vital threat component for impaired wound healing and lower extremities amputation. Also, PAD develops independently (there are always confounding and factors and effect modifier, e.g. vitamin deficiency like B6 and B12, which can explain the increase no of neuropathy, specially type-2 DM patient if treated with metformin it significantly increased B12 deficiency risk) as a result of diabetes.

In present study; PAD was found in 25.5% of the participants; among these 7.1% in type-1 diabetes and 18.4% in type-2 diabetes. When we see other studies: - this type of condition has

seen a 21 % (Abbas et al., 2007)**;** as we see it here as our results are consistent with the findings that are found in Tanzania. However, above the percentage found in the studies of 13% (Ramachandran, 2004)and12% (Fatma et al., 2007) this variation are due to age, duration and severity of diabetes, poor glycemic control, lifestyle of the study participants and mostly lack of gold standard diagnostic material (Doppler ultrasound) in the setup is noticeably subjective. This is in settlement with previous research in different African international locations (Abbas et al., 2005)**.**

Foot ulcer affects one of six diabetic patients during the course of their disease (Nina et al., 2013). Furthermore, the lifetime risk of a person with diabetes developing a foot ulcer could be as high as 25% (Desalu et al., 2011) and approximately 26.9% of the ulcers advanced to gangrene or amputation (Tseng, 2003). In the present study DFU was found in 55.1% of the study participants; among these 10.2% in type-1 diabetes and 44.9% in type-2 diabetes, while I examine it with different studies: - A cross-sectional cohort study which is done in Saudi Arabia, among 62,681 diabetic patients 95.45% of the patients was presented with Type-2 diabetes [Of this 94.27% of the patients had foot ulcer] and 4.55% of the patients was presented with Type-1 diabetes [Of this 5.73% of the patients had foot ulcer] (Al-Rubeaan et al., 2015), in another study which is done in Taiwan, from a total of 12, 531 case subjects DFU is found in 86.7% of the patients (Tseng, 2003).

Diabetic foot care education and level of practice

Diabetic foot cares have begun once the diagnosis of diabetes is made, even if there's no evidence of foot irregularities. The result of this examine showed that extra share of diabetic patients had a terrible know-how of diabetic foot care. In this examine, around one-third (18.4%) of type-2 DM patients were recognize the effects of diabetes Strolling fitness. The lack of understanding foot care in this examine is consistent with the have a look at carried out in Nigeria116 (33.0%)(Desalu et al., 2011)**.**

The knowledge of suitable foot care has been suggested to be definitely influenced by means of patient education which in turn reduces the risk of foot complications in this have a look at, only thirty-nine (39.8%) of type-1 DM and thirty-one (15.8%) participant were identified appropriate

foot care practice. This poor level of foot care practice in this look at is akin to the have a look at carried out in Nigeria 10.2% (Desalu et al., 2011)**.**

The diabetic foot program encompasses screening, examination, diagnostic tests, footwear recommendation, referrals, follow-ups and patient education. Preventive diabetic foot care education is an essential and a mandatory part inside the overall care of diabetes patients. Unfortunately, a sizable wide variety of patients have been not offered adequate self-care foot education. In the present study, 67.4% of type-1 and 79.6% of type-2 diabetes patients were not received self-care foot education from their health care provider, while I examine it with different studies: -A study which is done in rural Puducherry, India 79.1% of the study participants was not received self-care foot education from their health care provider (Suman et al., 2018); when we see other studies: -81% of DM participants were not received self-care foot education from their health care provider in a study done in Karachi, Pakistan(Riaz M, 2014); as we see it here our results are consistent with the findings that are found in Puducherry, India and Karachi, Pakistan. The deficiency inside the understanding may be because of no specified programs that encompass address diabetes education, unlike TB and HIV, which have many national programs and poor communication between the health care provider and the patients; additionally loss of counseling by health care provider as result of busy clinic schedule; and unavailability of diabetic foot care programs. Thus, patient education at the prevention of foot complication is imperative and must be integrated into the routine care of patients with diabetes.

7. Conclusion

The following conclusions were drawn from the present study conducted in foot mechanics in an individual with diabetes mellitus type-1 and type-2.

i. Type-2 diabetes patients have higher prevalence in developing diabetic foot deformities (claw/hammer taw, Hallux valgus, callusitis, and pes cavus) as compared to Type-1 diabetes patients.
ii. Type-2 diabetes patients have increment in developing PN, PAD, and foot ulceration as compared to Type-1 diabetes patients.
iii. Type-1 diabetes patients have increment in understanding the effects of diabetes on foot health and identifying appropriate foot care practice mobility as compared to Type-2 diabetes patients.
iv. Type-1 diabetes patients have increment in the overall level of foot care practice as compared to Type-2 diabetes patients
v. Regular foot screening, counseling and foot care education by health care provider ware suboptimal in Type-2 diabetes patients as compared to Type-1 diabetes patients.

8. Recommendation

I would like to forward the following recommendations for health professions, diabetic patients and Researchers

- Introduction of regular foot screening, risk factor modifications, appropriate footwear and identifying the at-risk foot during counseling.
- Providing individual and/or group education on the effect of diabetes on foot regularly.
- Providing educational material to improve awareness and to take preventive measure of diabetic foot complications.
- Researchers to use this data as a baseline to carry out further studies in the same conditions or other clinical scenarios.

9. Strength and Limitation of the study

9.1 Strengths

The strengths of the study:

1) To my knowledge, there was no research done on FOOT MECHANICS IN INDIVIDUALS WITH TYPE-1 AND TYPE-2 DIABETES MELLITUS: A COMPARATIVE STUDY. Therefore, this study offers local statistics on the prevalence of diabetic foot mechanics and its complications. It serves as a baseline research data for anyone who wishes to carry out further studies on diabetic foot.
2) This research contains multiple variables
3) The results of this study could serve as a wakeup call for clinicians and nurses establishing a patient and physician friendly educational programs that would enhance and sustain the knowledge and practice of foot care

9.2. Limitations

The limitations of the study were

1) This study was done in one institution (Mizan-Tapi university teaching hospital), due to time and cost limitations.
2) Design effect(this study was cross-sectional which was not able to establish the causal pathway of foot deformities)
3) The assessment of foot deformities relied on the subjective estimation of the researchers.

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10. Annex

Addis Ababa University, Collage of medicine and health science, Department of anatomy

MSc dissertation questionnaire

Date of completion: _____/_____/2018/19(G.C)

Dear respondent,

My name is _____ _____. These are questionnaires for the research study on **"FOOT MECHANICS IN INDIVIDUALS WITH TYPE-1 AND TYPE-2 DIABETES MELLITUS AMONG DIABETIC INDIVIDUALS WHO HAVE BEEN ON FOLLOW UP IN MIZAN-TAPI UNIVERSITY TEACHING HOSPITAL, BENCHI SHEKO ZONE, MIZAN TEFERI, ETHIOPIA."**The principal investigator is from Addis Ababa University, Department of anatomy and financially supported by university itself. As you are presented with diabetic foot disease where the study focuses, you are requested kindly to participation in the study by giving appropriate response and cooperation. The process of assessment and interview will take a maximum of 20 minutes. Be sure privacy issue will be kept confidential; so, freely respond to every questionnaires' and assessment. Moreover, pages of ethical consent form are attached with this questionnaire to know your willingness to participate. Thank you for your participation!

Consent form for participant

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have been answered to my satisfaction. I give consent voluntarily as a participant in this research.

Code of participant_____

Signature of participant_____

Date_____

If illiterate

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask question. I confirm that the individual has given consent freely.

Code of witness_____ AND thumb print of participant

Signature of witness_____

Date_____

Day/month/year

Statement by the researcher/person taking consent

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Name of researcher/person taking the consent_____

Signature of researcher/person taking the consent_____

Date_____

Date_____ **Code of Clients_____**

IDENTIFIER

Thank you for been voluntarily to participate in the study that focuses on biomechanical foot alteration in diabetic patient. Now I will ask you few questions about your feet.

Part I: - General History

A. Demographic Profile

1. Sex

   Male ☐ Female ☐

2. Age_____

3. Body weight_____

4. Height _____

5. Marital status_____

6. Educational status_____

7. Occupation _____

8. Exercise (Physical activity)_____

9. Smoking Yes ☐ NO ☐

10. Drinking alcohol Yes ☐ NO ☐

B. Clinical profile

1. Type of diabetics

   Type-1 ☐ Type-2 ☐

2. Duration of diabetics_____

3. Blood glucose level_____

   (RBS, FBS)

4. Blood pressure level_____

5. Drug history (current Medication)_____

   (Oral hypoglycemic agent and/or insulin)

6. History of other medical condition_____

Part II: - Assessments

Foot Assessment Checklist		
1. Ask the patient		
History of previous foot problem(ulcer, neuropathy)		☐Yes ☐ No
A history of foot numbness and tingling		☐Yes ☐ No
Neuropathic Symptoms		☐Yes ☐ No
Presence of current foot pain		
1.	Rest Pain	☐Yes ☐ No
2.	Intermittent claudication	☐Yes ☐ No

2. Look at Both Feet	
Infection	☐Yes ☐ No If the answer is **yes**, specify the type of infection_____
Edema	☐Yes ☐ No
Ulceration	☐Yes ☐ No
Calluses or corns	☐Yes ☐ No
Skin Breaks	☐Yes ☐ No
Skin color	☐Yes ☐ No
Nail Disorders	☐Yes ☐ No

Deformity	□Yes □ No If the answer is **yes**, specify the type of deformity_____

3. Blood pressure measurement

	Right	**Left**
Arm (Brachial)	_____mmHg	_____ mmHg
Foot (Dorsalis pedis)	_____ mmHg	_____ mmHg
Leg (Posterior tibial)	_____ mmHg	_____ mmHg

4. Vibration perception

	Right		**Left**	
1) **Great toe**	□Yes	□ No	□Yes	□ No
2) **Medial maleolli**	□Yes	□ No	□Yes	□ No
3) **Lateralmaleolli**	□Yes	□ No	□Yes	□ No

5. Assess footwear

Style	□Good	□ Poor
Condition	□Good	□ Poor
Fit	□Good	□ Poor

6. Knowledge /educational needs Assessment

Do you understand the effects of diabetes on foot health?	□Yes	□ No
Can you identify appropriate foot care practices?	□Yes	□ No
Have you ever attended a class on how to care for your feet	□Yes	□ No
Have you ever received education about foot care from your health care provider?	□Yes	□ No
Have you ever read any hand-outs/leaflets on foot care/foot wear?	□Yes	□ No

7. Self-care capacity/ Practice Assessment

Can you reach your feet for safe self-care?	□Yes	□ No
Do you regularly inspect your feet?	□Yes	□ No
Do you examine your feet?	□Yes	□ No
Do you walk barefoot?	□Yes	□ No

	Department of Anatomy Title: Department Research Ethics Review Committee (DRERC)

Meeting No:DRERC/01/09 Date: Jun 7,2019

Protocol Title: **"Foot mechanics in individuals with diabetes mellitus Type I and Type II: a comparative study."**		
Principal Investigator: Institute:	Biruk Endalkachew Mekonnen	
Elements Reviewed	☐ Attached	☐ Not attached
Decision of the meeting:	☒ Approved	☐ Approved with Recommendation
	☐ Resubmission	☐ Disapproved

1. Obligation of the PI-

i. Should comply with the standard international and national scientific and ethical guidelines
ii. All amendments and changes made in protocol and consent form needs DREC approval
iii. The PI should report Serious Adverse Event(SAE) within 10 days of the event
iv. End of the study, including thesis work and manuscript should be reported to the DREC

2. To IRB ☑

Follow up report expected in
3 Months_____ 6 Months ____ 9 Months _____ one year _____

Acting Secretary, DREC: Dept. of Anatomy Dr. Girma Seyoum (PhD)
Medical Faculty

Signature
Date: 10/06/2019

Department Stamp

ADDIS ABABA UNIVERSITY